DRAFT - February 19, 1996

FDA'S ILLEGAL AND EXTREME REGULATION OF TOBACCO

Industry Position: The goal of reducing youth smoking is laudable, but FDA lacks jurisdiction to regulate tobacco products, and the Agency's proposal is illegal and extreme.

On August 11, 1995, the Food and Drug Administration (FDA) proposed sweeping regulations restricting the sale, distribution, marketing, advertising and labeling of tobacco products. FDA's proposed regulations would ban tobacco vending machines and open-shelf product displays, and would prohibit virtually all tobacco advertising and promotional activity and would force tobacco companies to finance a $150 million-a-year antismoking campaign. FDA has been flooded with tens of thousands of letters in opposition to these extreme regulations from the advertising, retail, and tobacco industries, members of Congress, State and local government officials, and ordinary citizens.

- **Agency Power Grab.** For over 80 years, Congress has withheld jurisdiction over tobacco from FDA, choosing to regulate tobacco directly or delegating regulatory responsibility to a variety of agencies other than FDA. To support its claim of jurisdiction, FDA has come up with what only could be called a creative argument: that cigarettes are medical devices like hearing aids or pacemakers, and thus are subject to complete control by the Agency that regulates our food, medicines, cosmetics and medical devices. FDA's argument defies common sense: cigarettes are *not* medicines or medical devices and, consequently, FDA does *not* have jurisdiction over cigarettes.

- **Usurps State Prerogatives.** The FDA proposal subverts basic principles of federalism. As Congress recognized in the Synar Amendment passed in 1992, prevention of youth access to tobacco traditionally has been a prerogative of the States exercising their police power. FDA's regulations would override the Synar Amendment and the implementing regulations promulgated on January 19, 1996 by the Substance Abuse and Mental Health Services Administration (SAMHSA). Unlike the FDA approach, which -- contrary to the will of Congress -- would federalize tobacco regulation, the SAMHSA regulations encourage the *States* to take steps to reduce youth access to tobacco. While FDA hopes to reduce underage tobacco use by 50 percent over seven years, SAMHSA plans to increase compliance with State laws banning sale of tobacco to minors to a rate of 80 percent in the next several years, at a lower cost. Thus, the SAMHSA regulations will accomplish more than FDA's regulations in a shorter time for less money with much less federal interference.

- **Advertising Restrictions Violate First Amendment.** FDA's proposed rules would ban certain forms of tobacco advertising altogether and otherwise would make it exceedingly difficult, if not impossible, for cigarette and smokeless tobacco manufacturers to advertise and promote their products to adult consumers. FDA has offered no reason to believe that advertising restrictions are necessary; restrictions on sale and distribution -- if properly enforced -- should be sufficient to reduce underage tobacco use without curbing

2041186011

Source: https://www.industrydocuments.ucsf.edu/docs/zhgc0003

constitutionally protected expression. Moreover, FDA has not demonstrated that its proposed restrictions on tobacco advertising and promotion "will in fact" reduce tobacco use among persons under the age of 18, as required by the Supreme Court's commercial speech decisions. Simply put, FDA's proposed advertising restrictions would impermissibly reduce the adult population to reading only what the Agency considers to be fit for children. FDA's proposed restrictions are unlikely to reduce tobacco use by young people, but those restrictions certainly would violate the First Amendment and other constitutional protections.

- **Manipulation of Social Attitudes.** FDA claims that its regulations are intended to protect minors. However, FDA's Draconian advertising restrictions reveal FDA's real goal: to use the power of the federal government to stigmatize smoking and delegitimize cigarettes in our culture. FDA seeks to force tobacco product manufacturers themselves to undertake a $150 million-a-year TV-based antismoking campaign. The First Amendment forbids the government from forcing legitimate businesses to advertise against their own products. CITE (?) - what (a the calif. utility case?

- **Costs to Businesses and Communities.** A report for the cigarette companies by the Barents Group, a subsidiary of KPMG Peat Marwick, estimates that FDA's proposed tobacco regulations would ~~cost consumers, retailers and cigarette makers from~~ $748 million to more than $ 1 billion in one-time costs, and between $826 million and $867 million per year in recurring costs. When the potential loss of promotional payments to retailers and the impact on the advertising industry are taken into account, additional recurring costs could range from $1.25 billion to $3.25 billion per year.

result in

I'm not sure about these analogy in the present context.

2041186012

Source: https://www.industrydocuments.ucsf.edu/docs/zhgc0003